Remarks

This Amendment is being submitted in response to the September 13, 2011 Office Action in the above-identified patent application.

Interview Summary

Applicants wish to thank the Examiner for the applicant-initiated telephonic interview conducted with applicants' undersigned attorney on October 5, 2011. The issues discussed related to clarification of the §112 rejections. No issues were resolved during the telephonic interview, but the Examiner's clarification was helpful for directing and formulating applicants' response as presented herein.

Status of the Claims

Original claims 1-52 were canceled when new claims 53-80 were added during prosecution of the subject application. Claims 66 and 72-75 were also previously canceled.

Remaining claims 53-65, 67-71, and 76-80, were subject to a Restriction Requirement dated July 14, 2011. In applicants' August 12, 2011 response to the Restriction Requirement, Group I claims 53, 61, 67-68, 76-77 and 80 were elected and claims 54-60, 62-65, 69-71, and 78-79 were withdrawn from consideration.

As shown in the accompanying Listing of Claims, claim 53 has now been further amended to specify the "bottom" and "top" layers in a tablet comprising two or more active segments. Support for this amendment is provided in the specification, particularly in the drawings (see Figs. 13-22) and at page 21, lines 1-12 describing the orientation of the tablets in the tablet die and their corresponding depiction in the drawings.

The previously withdrawn claims 54-60, 62-65, 69-71, and 78-79, as well as elected claim 80, are canceled by the above amendment.

Request for Continued Examination

The current Office Action acknowledges the Request for Continued Examination (RCE), and fee, submitted August 30, 2010. Applicants appreciate the Examiner's careful consideration and entry of the RCE, and the consequent withdrawal of the finality of the previous Office Action.

Double Patenting

Applicants further acknowledge the acceptance of the Terminal Disclaimers submitted in the application regarding the obviousness-type double patenting rejection of claims 53-71and 76-80.

Claim Rejections under 35 USC 112

Claims 53, 61, 67-68, and 76-77 stand rejected under 35 USC §112, second paragraph as being indefinite. Claim 53 is cited as being unclear as to its recitation of an "outer" inactive segment. To clarify, an embodiment of a tablet as defined in claim 53 is exemplified in Figs. 13-14, and 16-19 wherein the tablet is a bi-layer configuration where the active (shaded) layer forms one, or more than one, "outer" segment from that layer. The inactive (unshaded) layer forms another "outer" layer, which is a single (undivided) inactive segment of the tablet. This recitation of the layer forming "outer" segments or layers is intended to distinguish this configuration from a tablet as shown in Fig. 20, where the inactive (unshaded) layer is not an "outer" segment, but rather an "inner" segment formed between two active outer layers.

Applicants note that claim 53 is currently amended to further specify that the active and inactive layers form "bottom" and "top" layers of the tablet, as oriented in the tablet die. This recitation provided in the amended claims is believed to further clarify the configuration and orientation of the tablet for purposes of claim definiteness.

In addition, the Office Action indicates that the recitation of the score in the bottom active segment (layer) is unclear because the "breaking segment" is not scored. However, as shown in Figs. 14A and 14B, as well as 17A and 17B, the term "breaking segment" is used to refer to the inactive layer which "breaks" without regard to accuracy or precision. In other words, the inactive layer forms a segment that may break unevenly or in a plurality of angles without affecting the dose division. On the other hand, the active layer is deeply scored (greater than 50% through that segment, as claimed, and shown in Figs. 13, 16 and 18) to form a pre-divided segment that only minimally "breaks" (see Figs 14A and 14B showing a minimal portion of the active segment breaking), if it breaks at all (see Figs. Figs. 17A and 17B showing no break through the active segment). Therefore, applicants respectfully submit that the non-scored, inactive layer or segment recited as the "breaking segment" is clear, as presented.

The Office Action further raises the issue of clarity regarding claims 76-77. Claim 76 is directed to a deeply scored tablet of the invention which is then coated with an inert coating, such as a spray coating or a coating applied by a pan-coating procedure. That inert coating can, alternatively, be provided by encapsulation of the scored tablet within a capsule, as claimed in claim 77.

The score can clearly be utilized for breaking a coated tablet of claim 76, or by removing the tablet from the capsule (claim 77) for breaking prior to administration of a partial dose. The score is not needed for breaking in the instance of administering a whole tablet within the capsule, which can be provided to facilitate swallowing of the whole-dose dosage form. Applicants respectfully submit that a person of ordinary skill in the art would readily understand the coating or capsule embodiments of claims 76-77.

It is believed that the above explanation clarifies the terminology used in the claims and that claims 53, and 76-77 are definite for purposes of 35 USC §112. Reconsideration and withdrawal of the rejection is respectfully requested.

Claim Rejections under 35 USC §103

The rejection of claims 53-71 and 76-80 citing Lieberman have been withdrawn. Applicants appreciate the Examiner's careful consideration of applicants' prior remarks and the withdrawal of this rejection.

A new ground of rejection has been made against claim 80 as being obvious over Hess, in view of UROXATRAL. However, claim 80 has been canceled by the above amendment, which makes moot the current rejection. Reconsideration and withdrawal of the rejection of claim 80 is respectfully requested.

The claims, as currently amended, are believed to be unobvious in view of these cited references. The current claims specify that the score is formed in the "bottom" (active) segment, using an embossed bottom punch, during the compressed tableting process. The Hess reference describes a tablet which is scored from a top punch, or a top and a bottom punch – but not a bottom punch only.

This bottom scoring of the subject tablets advantageously provides a divisible tablet manufactured without certain disadvantages unexpectedly discovered by the applicants while developing the subject tablets using an embossed top punch to form a score in the top layer. By forming the score in the bottom layer, applicants arrived at a tablet having certain advantages, including:

more complete separation of the layer forming the active segment or segments;

allows for "tamping" which maintains layer uniformity and prevents extrusion or mixing of active into the inactive layer.

Providing a score in the top layer using an embossed top punch cannot provide these advantages.

Applicants have discovered disadvantages for a top-scored, layered tablet. For example, layer uniformity is optimized by tamping of the first layer because tamping facilitates leveling of the first layer and provides a flat, level, or planar surface upon which the second layer is disposed. Tamping the first layer using an embossed top punch will necessarily and disadvantageously "score" the first layer, forming a depression in that layer. Subsequent layers then fill in the depression, forming an uneven or non-uniform interface between the two layers.

The differences resulting from a top-scored tablet versus a bottom-scored tablet are evident from the photographs provided in the attached Appendix. Fig. 1 shows a top-scored tablet and clearly illustrates the depression formed in the bottom layer resulting from the embossed top punch. The interface of the layers is not flat or level and the active top layer is pushed into the upper plane of the inactive layer. In Fig. 2 of the Appendix, a tablet scored using an embossed bottom punch illustrates the advantageous flat, level interface between the bottom and top layers which allows for less surface area exposure of the active layer following tablet division.

This non-uniformity of layers is undesired aesthetically and functionally. Functionally, the depression formed by an embossed top punch provides a larger exposed surface area for the active layer when the tablet is divided at the score, which can result in more rapid dissolution of the active. A preferred embodiment of the subject invention is a tablet that minimizes the exposed surface area of the active upon tablet division.

Scored bi-layers have been described but fail to describe and recognize the need for tamping the first layer. Hess fails to describe tamping and, in a tablet scored on only a single surface (See Fig. 1 and Example 1), erroneously teaches that the embossing can be on either punch. As stated, an embossed top punch will disadvantageously provide a depression in the first layer, leading to a non-planar interface between the layers which can add surface area to the broken active layer and thereby negatively affect the dissolution rate. Clearly, the Table provided at page 3, col. 2, of Hess shows increased release times for the active in each instance for the halved tablet versus the whole tablet.

The reference of Hess is further distinguishable from the subject invention in view of its teaching of a flat "band" around the side circumference of the "rod-shaped" tablet as shown in the accompanying drawings. The subject invention is not limited to rod-shaped tablets and preferably is in the form of round tablets. Moreover, the subject tablets do not have the flat band around their circumference, since coating of a tablet having this feature may cause "twinning"—adherence of the tablets to one another during spray coating or pan coating of the tablets. Thus, Hess teaches inoperable methods of forming the described tablets and does not enable the manufacture of the tablets as described.

Applicants believe that the pending claims are in condition for allowance and respectfully request issuance of the Notice of Allowance upon reconsideration.

Applicants invite the Examiner to contact the undersigned at the address and/or phone number provided below if clarification or additional information is needed on any of these matters.

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Respectfully submitted,

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APPENDIX

UPPER PUNCH SCORE VS. LOWER PUNCH SCORE

Prototype experiments Accu-Break bi-layer tablet technology

FIG. 1: Bi-layer tablet scored with embossed upper (top) punch

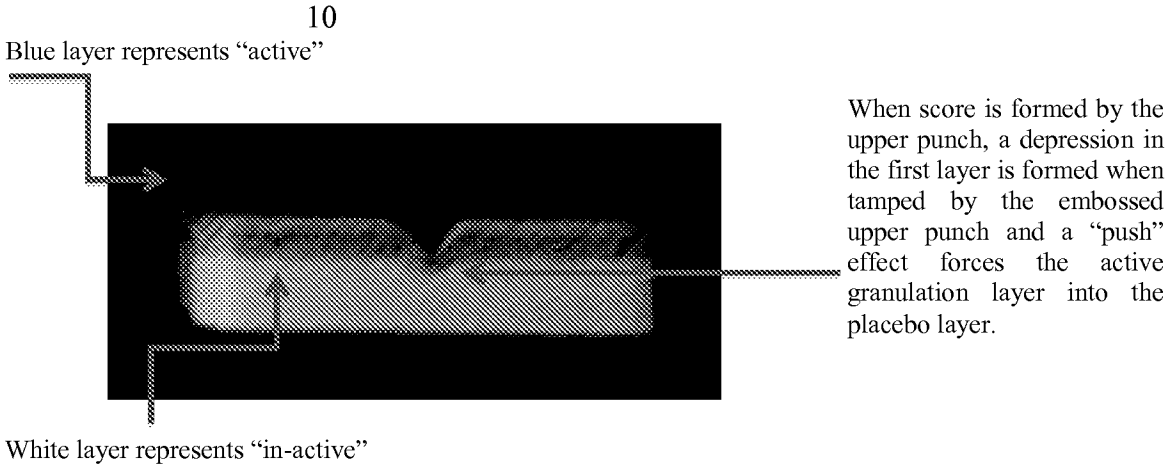

FIG. 2: Bi-layer tablet scored with embossed lower (bottom) punch